

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property
Organization
International Bureau



(43) International Publication Date
22 April 2004 (22.04.2004)

PCT

(10) International Publication Number
WO 2004/034056 A3

(51) International Patent Classification⁷: **G01N 33/558**,
33/543

(21) International Application Number:
PCT/US2003/031859

(22) International Filing Date: 8 October 2003 (08.10.2003)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/416,676 8 October 2002 (08.10.2002) US

(71) Applicant and

(72) Inventor: NYLESE, Tara [US/US]; 819 Chestnut Court,
Marco Island, FL 34145 (US).

(74) Agents: BEUSSE, James, H. et al.; Beusse Brownlee
Bowdoin & Wolter, P.A., 390 N. Orange Avenue, Suite
2500, Orlando, FL 32801 (US).

(81) Designated States (national): AE, AG, AL, AM, AT, AU,
AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU,

CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH,
GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC,
LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW,
MX, MZ, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC,
SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA,
UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States (regional): ARIPO patent (GH, GM,
KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW),
Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM),
European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE,
ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO,
SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM,
GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

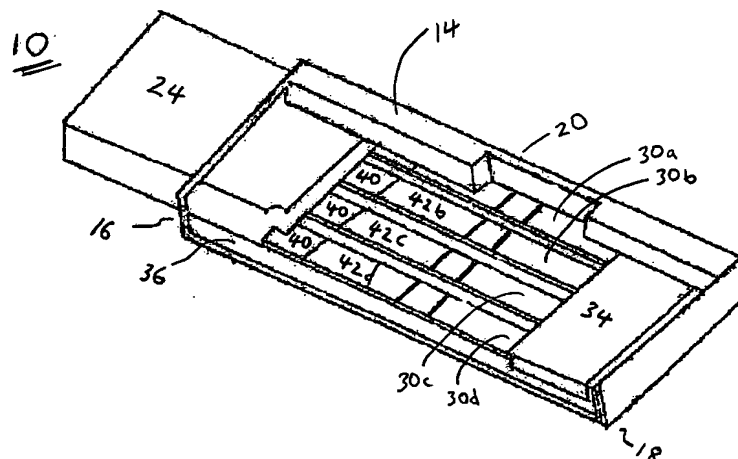
Published:

- with international search report
- before the expiration of the time limit for amending the
claims and to be republished in the event of receipt of
amendments

(88) Date of publication of the international search report:
12 August 2004

For two-letter codes and other abbreviations, refer to the "Guid-
ance Notes on Codes and Abbreviations" appearing at the begin-
ning of each regular issue of the PCT Gazette.

(54) Title: PORTABLE DIAGNOSTIC DEVICE AND METHOD FOR DETERMINING TEMPORAL VARIATIONS IN CON-
CENTRATIONS



(57) Abstract: A rapid assay concentration device. In one form, the device includes a substrate and a plurality of elongated mem-
branes on the substrate. At least one capture zone is formed in each membrane. Each capture zone is responsive to the presence of a
target chemical in the fluid. Capture zones on different membranes have different threshold levels of response to the chemical. In a
method for monitoring temporal changes of analyte levels in a source multiple test devices are provided, with each device including
a plurality of regions. Each region is responsive at a different sensitivity level to indicate presence of the analyte. A source sample
is brought into contact with a first of the test devices to determine whether the source contains a level of analyte sufficient to induce
a response thereto in one or more of the test unit regions. A different sample from the source is brought into contact with a second
of the test devices to determine whether the source contains a level of analyte sufficient to induce a response thereto in one or more
regions of the second test device.

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 03/31859

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 G01N33/558 G01N33/543

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 G01N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ, MEDLINE, BIOSIS, EMBASE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 93/15230 A (ABBOTT LAB) 5 August 1993 (1993-08-05) abstract page 6, line 20 -page 19, line 20 example 1 claims 1-10 figure 5	2-9, 22-24 1,10-21
Y		
X	US 6 203 757 B1 (CHAN LIANG ET AL) 20 March 2001 (2001-03-20) abstract column 3, line 60 -column 9, line 21 claims 1-19 -/--	2,4-8, 22-24

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- *Z* document member of the same patent family

Date of the actual completion of the international search

10 May 2004

Date of mailing of the international search report

23/06/2004

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Vanhalst, K

INTERNATIONAL SEARCH REPORT

In tional Application No
PCT/US 03/31859

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 98/39657 A (QUIDEL CORP ; ROWLEY GERALD (US); BOEHRINGER HANS (US); PRONOVOST A) 11 September 1998 (1998-09-11) abstract page 4, line 20 -page 6, line 14 examples 1-14 claims 1-120 figure 2	2,4-8, 22-24
Y	O'CONNOR J F ET AL: "Differential urinary gonadotrophin profiles in early pregnancy and early pregnancy loss." PRENATAL DIAGNOSIS. ENGLAND DEC 1998, vol. 18, no. 12, December 1998 (1998-12), pages 1232-1240, XP001098498 ISSN: 0197-3851 abstract	1,10-21
A	DART R G ET AL: "Rate of change of serial beta-human chorionic gonadotropin values as a predictor of ectopic pregnancy in patients with indeterminate transvaginal ultrasound findings." ANNALS OF EMERGENCY MEDICINE. UNITED STATES DEC 1999, vol. 34, no. 6, December 1999 (1999-12), pages 703-710, XP008029725 ISSN: 0196-0644 abstract	1,10-21
A	EP 0 362 809 A (BOEHRINGER BIOCHEMIA SRL) 11 April 1990 (1990-04-11) abstract	1-24
A	US 6 156 271 A (MAY KEITH) 5 December 2000 (2000-12-05) abstract	1-24
A	US 5 786 220 A (PRONOVOST ALLAN D ET AL) 28 July 1998 (1998-07-28) abstract	1-24
A	WO 02/44729 A (LEE HELEN ; HUANG LING (GB); DINEVA MAGDA ANASTASSOVA (GB); HU HSIA) 6 June 2002 (2002-06-06) abstract	1-24

INTERNATIONAL SEARCH REPORT
Information on patent family members

International Application No
PCT/US 03/31859

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 9315230	A	05-08-1993	AU 3439693 A CA 2128320 A1 EP 0643777 A1 JP 7503540 T WO 9315230 A1 US 5780308 A	01-09-1993 05-08-1993 22-03-1995 13-04-1995 05-08-1993 14-07-1998
US 6203757	B1	20-03-2001	NONE	
WO 9839657	A	11-09-1998	AU 6450698 A WO 9839657 A1	22-09-1998 11-09-1998
EP 0362809	A	11-04-1990	IT 1227293 B AT 100591 T DE 68912489 D1 EP 0362809 A1 JP 2136137 A US 5145789 A	05-04-1991 15-02-1994 03-03-1994 11-04-1990 24-05-1990 08-09-1992
US 6156271	A	05-12-2000	GB 2322192 A AU 742664 B2 AU 5537798 A CA 2229331 A1 DE 19806291 A1 ES 2144358 A1 FR 2759782 A1 IE 980070 A1 IT T0980115 A1 JP 10232189 A NL 1008254 C2 NL 1008254 A1	19-08-1998 10-01-2002 20-08-1998 14-08-1998 20-08-1998 01-06-2000 21-08-1998 26-08-1998 13-08-1999 02-09-1998 09-03-1999 18-08-1998
US 5786220	A	28-07-1998	WO 9634287 A1	31-10-1996
WO 0244729	A	06-06-2002	AU 2211702 A EP 1340083 A1 WO 0244729 A1 US 2004048395 A1	11-06-2002 03-09-2003 06-06-2002 11-03-2004